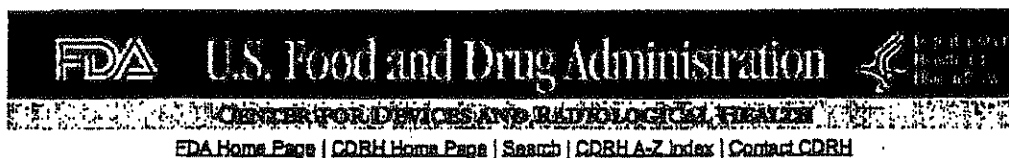


Manufacturer and User Facility Device Experience (MAUDE) Data... <http://www.accessdata.fda.gov/scripts/cdrh/cddocs/cimaUDE/Detail...>



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Adverse Event Report

**SMITH & NEPHEW INC., ORTHOPAEDIC DIV. ECHELON
HIP STEM**

[back to search results](#)

Catalog Number 71340912

Event Date 02/04/2003

Event Type Injury Patient Outcome Hospitalization; Required Intervention

Event Description

It is reported that revision surgery took place because the stem broke in two.

[Search Alerts/Recalls \(Contained in Enforcement Reports\)](#)

(After selecting, enter device information to search Alerts/Recalls)

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Brand Name ECHELON

Type of Device HIP STEM

Baseline Brand Name ECHELON

Baseline Generic Name FEMORAL STEM

Baseline Catalogue Number 71340912

Baseline Device Family ECHELON POROUS REVISION HIP SYSTEM

Baseline Device 510(K) Number K963486

Baseline Device PMA Number

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Manufacturer and User Facility Device Experience (MAUDE) Data... <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Deta...>

Shelf Life(Months) NA
 Date First Marketed 11/27/1996
 Manufacturer (Section F) SMITH & NEPHEW INC.,
 ORTHOPAEDIC DIV.
 1450 Brooks Road
 Memphis TN 38116
 Manufacturer (Section D) SMITH & NEPHEW INC.,
 ORTHOPAEDIC DIV.
 1450 Brooks Road
 Memphis TN 38116
 Manufacturer Contact Pam Peden, Specialist
 1450 Brooks Road
 Memphis, TN 38116
 (901) 399 -5844
 Device Event Key 431938
 MDR Report Key 442965
 Event Key 419308
 Report Number 1020279-2003-00014
 Device Sequence Number 1
 Product Code JDI
 Report Source Manufacturer
 Source Type Health Professional, Company Representative
 Reporter Occupation Physician
 Type of Report Initial
 Report Date 02/05/2003
 1 Device Was Involved In the Event
 1 Patient Was Involved In the Event
 Date FDA Received 02/12/2003
 Is This An Adverse Event Report? Yes
 Is This A Product Problem Report? No
 Device Operator Health Professional
 Device Catalogue Number 71340912
 Device LOT Number 90100809

Manufacturer and User Facility Device Experience (MAUDE) Data... <http://www.accessdata.fda.gov/scripts/cdrh/cdrdocs/cfMAUDE/detail...>

Was Device Available For Evaluation? Yes
 Is The Reporter A Health Professional? Yes
 Was the Report Sent to FDA? No
 Device Age 34 mo
 Event Location Hospital
 Date Manufacturer Received 02/05/2003
 Was Device Evaluated By Manufacturer? No
 Date Device Manufactured 01/01/1999
 Is The Device Single Use? Yes
 Is the Device an Implant? Yes
 Is this an Explanted Device?
 Type of Device Usage Initial

Database last updated on July 27, 2007

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Adverse Event Report
**SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON POROUS
BOWED STEM**
[back to search
results](#)
Catalog Number 71340412**Event Date** 07/29/2002**Event Type** Injury **Patient Outcome** Hospitalization; Required Intervention**Event Description**

It was reported that revision surgery was performed due to fracture of the stem. Surgeon suspects poor proximal support.

Manufacturer Narrative

Upon review of xrays, the co's medical advisor report concerns that the stem was well fixed distally but not proximally.

Search Alerts/Recalls
[new search](#) | [submit an adverse event report](#)
Brand Name ECHELON**Type of Device** POROUS BOWED STEM**Baseline Brand Name** ECHELON**Baseline Generic Name** HIP PROSTHESIS**Baseline Catalogue Number** 71340412**Baseline Device Family** ECHELON HIP SYSTEM**Baseline Device 510(K) Number** K963486**Baseline Device PMA Number****Baseline Preamendment?** No**Transitional?** No**510(K) Exempt?** No**Shelf Life(Months)** NA**Date First Marketed** 11/27/1996

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.

Manufacturer (Section F) 1450 Brooks Road
Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.
1450 Brooks Road
Memphis TN 38116

Manufacturer Contact Carolyn Shelton, Supervisor
1450 Brooks Road
Memphis , TN 38116
(901) 399 -6654

Device Event Key 415160

MDR Report Key 426110

Event Key 403099

Report Number 1020279-2002-00069

Device Sequence Number 1

Product Code JDH

Report Source Manufacturer

Source Type Health Professional, Company Representative

Reporter Occupation Physician

Type of Report Initial

Report Date 11/05/2002

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 11/05/2002

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340412

Device LOT Number 90100783

Was Device Available For Evaluation? Device Returned To Manufacturer

Date Returned to Manufacturer 10/18/2002

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age 34 mo

Event Location Hospital

Date Manufacturer Received 10/18/2002

Was Device Evaluated By Manufacturer? No

Date Device Manufactured 01/01/1999

Is The Device Single Use? Yes

Is the Device an Implant? Yes

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

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Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL STEM

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Catalog Number 71340213

Event Date 05/17/2002

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that revision surgery was performed due to the breakage of the femoral component.

Search Alerts/Recalls

[new search](#) | [submit an adverse event report](#)

Brand Name ECHELON

Type of Device FEMORAL STEM

Baseline Brand Name ECHELON

Baseline Generic Name FEMORAL STEM

Baseline Catalogue Number 71340213

Baseline Device Family ECHELON POROUS REVISION HIP SYSTEM

Baseline Device 510(K) Number K963486

Baseline Device PMA Number

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.
1450 Brooks Road
Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.
1450 Brooks Road

Memphis TN 38116

Manufacturer Contact Ivan Harlan, Mgr.
1450 Brooks Road
Memphis , TN 38116
(901) 399 -6660

Device Event Key 388348

MDR Report Key 399300

Event Key 377330

Report Number 1020279-2002-00037

Device Sequence Number 1

Product Code JDI

Report Source Manufacturer

Source Type Health Professional

Reporter Occupation Physician

Type of Report Initial

Report Date 06/14/2002

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 06/14/2002

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340213

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age unknown

Event Location Hospital

Date Manufacturer Received 05/22/2002

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Is The Device Single Use? Yes

Is the Device an Implant? Yes

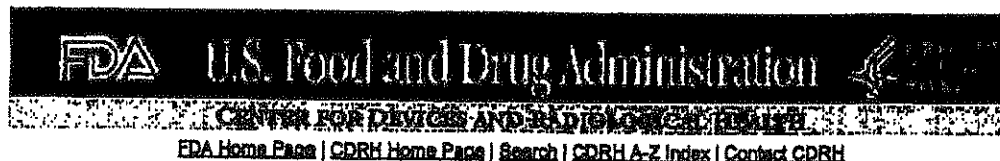
Is this an Explanted Device?

Type of Device Usage Initial

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Adverse Event Report

SMITH & NEPHEW INC., ORTHOPAEDIC DIV. ECHELON FEMORAL STEM

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Catalog Number 71340813

Event Date [REDACTED]

Event Type Injury Patient Outcome Hospitalization; Required Intervention

Event Description

It was reported that revision surgery was performed due to the [REDACTED] femoral stem. The device was replaced with a similar device. The patient expired two days following the revision surgery due to unrelated causes.

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(After selecting, enter device information to search Alerts/Recalls)

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Brand Name ECHELON

Type of Device FEMORAL STEM

Baseline Brand Name ECHELON

Baseline Generic Name FEMORAL STEM

Baseline Catalogue Number 71340813

Baseline Device Family ECHELON POROUS REVISION HIP SYSTEM

Baseline Device 510(K) Number K963486

Is Baseline PMA Number Provided? No

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW INC., ORTHOPAEDIC DIV.
1450 Brooks Road
Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW INC., ORTHOPAEDIC
DIV.
1450 Brooks Road
Memphis TN 38116

Manufacturer Contact Ivan Harian, Manager
1450 Brooks Road
Memphis, TN 38116
(901) 399-6860

Device Event Key 378286

MDR Report Key 389236

Event Key 367581

Report Number 1020279-2002-00028

Device Sequence Number 1

Product Code JDI

Report Source Manufacturer

Source Type Health Professional, Company Representative

Reporter Occupation Other

Type of Report Initial

Report Date 04/22/2002

1 Device Was Involved In the Event

1 Patient Was Involved In the Event

Date FDA Received 04/22/2002

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340613

Device LOT Number 80400008

Was Device Available For Evaluation? Device Returned To Manufacturer

Date Returned to Manufacturer 04/05/2002

Is The Reporter A Health Professional? No

Was the Report Sent to FDA? No

Device Age 7 mo

Event Location Hospital

Date Manufacturer Received 03/28/2002

Was Device Evaluated By Manufacturer? No

Date Device Manufactured 04/01/1998

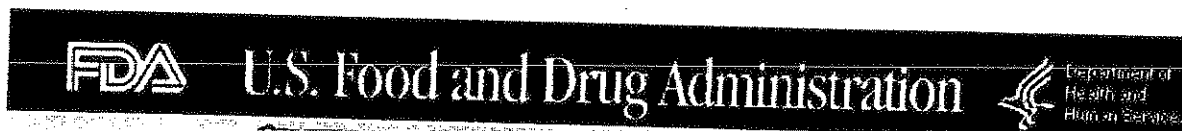
Is The Device Single Use? Yes

Is the Device an Implant? Yes
Is this an Explanted Device?
Type of Device Usage Initial

Database last updated on June 29, 2007

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Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIV. ECHELON FEMORAL COMPONENT

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Catalog Number 71340412

Event Date 07/01/2001

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that revision surgery was performed due to a breakage of the femoral stem.

Search Alerts/Recalls

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Brand Name ECHELON

Type of Device FEMORAL COMPONENT

Baseline Brand Name ECHELON

Baseline Generic Name HIP PROSTHESIS

Baseline Catalogue Number 71340412

Baseline Device Family ECHELON HIP SYSTEM

Baseline Device 510(K) Number K963486

Baseline Device PMA Number

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.
1450 Brooks Road
Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC., ORTHOPAEDIC DIV.
1450 Brooks Road
Memphis TN 38116

Ivan Harlan, Sr.
Manufacturer Contact 1450 Brooks Road
Memphis, TN 38116
(901) 399-6660

Device Event Key 335736

MDR Report Key 346419

Event Key 326239

Report Number 1020279-2001-00046

Device Sequence Number 1

Product Code JDH

Report Source Manufacturer

Source Type Health Professional

Reporter Occupation Physician

Type of Report Initial

Report Date 08/06/2001

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 08/08/2001

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340412

Device LOT Number 90300320

Was Device Available For Evaluation? Device Returned To Manufacturer

Date Returned to Manufacturer 07/12/2001

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age 23 mo

Event Location Hospital

Date Manufacturer Received 07/06/2001

Was Device Evaluated By Manufacturer? No

Date Device Manufactured 03/01/1999

Is The Device Single Use? Yes

Is the Device an Implant? Yes

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

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Adverse Event Report
**SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION ECHELON
FEMORAL STEM**
[back to search
results](#)
Catalog Number 71340215**Event Date** 10/30/2000**Event Type** Injury **Patient Outcome** Hospitalization; Required Intervention**Event Description**

It was reported that revision surgery was required due to breakage of the stem.

Search Alerts/Recalls
[new search](#) | [submit an adverse event report](#)
Brand Name ECHELON**Type of Device** FEMORAL STEM**Baseline Brand Name** ECHELON**Baseline Generic Name** FEMORAL STEM**Baseline Catalogue Number** 71340215**Baseline Device Family** ECHELON POROUS REVISION HIP SYSTEM**Baseline Device 510(K) Number** K963486**Baseline Device PMA Number****Baseline Preamendment?** No**Transitional?** No**510(K) Exempt?** No**Shelf Life(Months)** NA**Date First Marketed** 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW, INC., ORTHOPAEDIC
DIVISION
1450 Brooks Road
Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC., ORTHOPAEDIC
DIVISION

1450 Brooks Road
Memphis TN 38116

Manufacturer Contact Ivan Harlan, Sr. Qa Eng
1450 Brooks Road
Memphis, TN 38116
(901) 399-6660

Device Event Key 303465

MDR Report Key 313790

Event Key 294963

Report Number 1020279-2001-00007

Device Sequence Number 1

Product Code JDI

Report Source Manufacturer

Source Type Health Professional

Reporter Occupation Physician

Type of Report Initial

Report Date 01/26/2001

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 01/26/2001

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340215

Device LOT Number 80707510

Was Device Available For Evaluation? Yes

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age 1.5 yr

Event Location Hospital

Date Manufacturer Received 01/11/2001

Was Device Evaluated By Manufacturer? No

Date Device Manufactured 07/01/1998

Is The Device Single Use? Yes

Is the Device an Implant? Yes

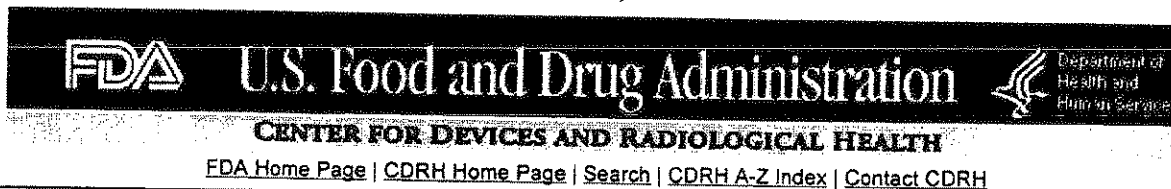
Is this an Explanted Device?

Type of Device Usage Initial

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Adverse Event Report

SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION ECHELON HIP PROSTHESIS

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Event Date 12/06/2000

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that a split in the proximal femur was noted on a post-operative x-ray. Add'l surgery with cerclage wire was subsequently required for internal fixation of the fracture.

Search Alerts/Recalls

[new search](#) | [submit an adverse event report](#)

Brand Name ECHELON

Type of Device HIP PROSTHESIS

Baseline Device 510(K) Number

Baseline Device PMA Number

Manufacturer (Section F) SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION
 1450 E. Brooks Road
 Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION
 1450 E. Brooks Road
 Memphis TN 38116

Manufacturer Contact Ivan Harlan, Sr. Engineer
 1450 Brooks Road
 Memphis, TN 38116
 (901) 399 -6660

Device Event Key 301129

MDR Report Key 311320

Event Key 292615

Report Number 1020279-2001-00003

Device Sequence Number 1

Product Code JDI

Report Source Manufacturer

Source Type Health Professional

Reporter Occupation Physician

Type of Report Initial

Report Date 01/04/2001

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 01/04/2001

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Event Location Hospital

Date Manufacturer Received 12/08/2000

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Is The Device Single Use? No Answer Provided

Is the Device an Implant? Yes

Is this an Explanted Device?

Type of Device Usage Initial

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Adverse Event Report

**SMITH & NEPHEW, INC., ORTHOPAEDIC DIVISION ECHELON
FEMORAL STEM**

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results](#)

Catalog Number 71340114

Event Date 07/11/2000

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that revision surgery was performed due to the breakage of the femoral stem.

Search Alerts/Recalls

[new search](#) | [submit an adverse event report](#)

Brand Name ECHELON

Type of Device FEMORAL STEM

Baseline Brand Name ECHELON

Baseline Generic Name FEMORAL STEM

Baseline Catalogue Number 71340114

Baseline Device Family ECHELON POROUS REVISION HIP STEM

Baseline Device 510(K) Number K963486

Baseline Device PMA Number

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW, INC., ORTHOPAEDIC
DIVISION
1450 Brooks Road
Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC., ORTHOPAEDIC
DIVISION

1450 Brooks Road
Memphis TN 38116

Manufacturer Contact Ivan Harlan, Sr Qa Eng
1450 Brooks Road
Memphis, TN 38116
(901) 399-6660

Device Event Key 290509

MDR Report Key 300139

Event Key 281969

Report Number 1020279-2000-00043

Device Sequence Number 1

Product Code JDI

Report Source Manufacturer

Source Type Company Representative

Reporter Occupation Physician

Type of Report Initial

Report Date 10/09/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 10/10/2000

Is This An Adverse Event Report? No

Device Operator Health Professional

Device Catalogue Number 71340114

Device LOT Number 80303559

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age 1 yr

Event Location Hospital

Date Manufacturer Received 10/05/2000

Was Device Evaluated By Manufacturer? Device Not Returned To Manufacturer

Date Device Manufactured 03/01/1998

Is The Device Single Use? Yes

Is the Device an Implant? Yes

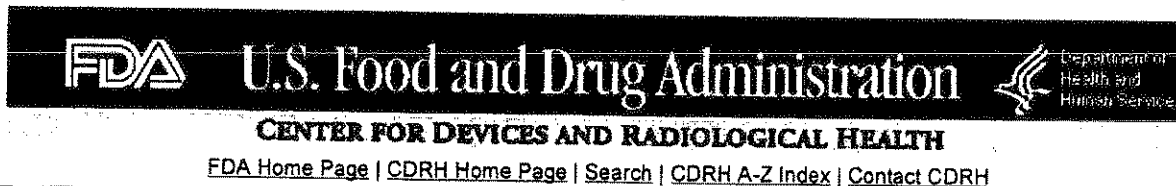
Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

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Adverse Event Report

**SMITH & NEPHEW, INC./ORTHOPAEDIC DIVISION ECHELON
 FEMORAL STEM**

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 results](#)

Catalog Number 71340712

Event Date 09/06/2000

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that revision surgery was performed due to the breakage of the femoral stem.

Search Alerts/Recalls

[new search](#) | [submit an adverse event report](#)

Brand Name ECHELON

Type of Device FEMORAL STEM

Baseline Brand Name ECHELON

Baseline Generic Name FEMORAL STEM

Baseline Catalogue Number 71340712

Baseline Device Family ECHELON POROUS REVISION HIP STEM

Baseline Device 510(K) Number K963486

Baseline Device PMA Number

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW, INC./ORTHOPAEDIC
 DIVISION
 1450 Brooks Road
 Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC./ORTHOPAEDIC
 DIVISION

1450 Brooks Road
Memphis TN 38116

Manufacturer Contact Ivan Harlan, Sr. Engineer
1450 Brooks Rd
Memphis, TN 38116
(901) 399 -6660

Device Event Key 289579

MDR Report Key 299159

Event Key 281049

Report Number 1020279-2000-00042

Device Sequence Number 1

Product Code JDI

Report Source Manufacturer

Source Type Health Professional,Distributor

Reporter Occupation Physician

Type of Report Initial

Report Date 10/05/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 10/05/2000

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340712

Device LOT Number 81106797

Was Device Available For Evaluation? Device Returned To Manufacturer

Date Returned to Manufacturer 09/08/2000

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age 5 mo

Event Location Hospital

Date Manufacturer Received 09/06/2000

**Was Device Evaluated By
Manufacturer?** No

Date Device Manufactured 11/01/1998

Is The Device Single Use? Yes

Is the Device an Implant? Yes

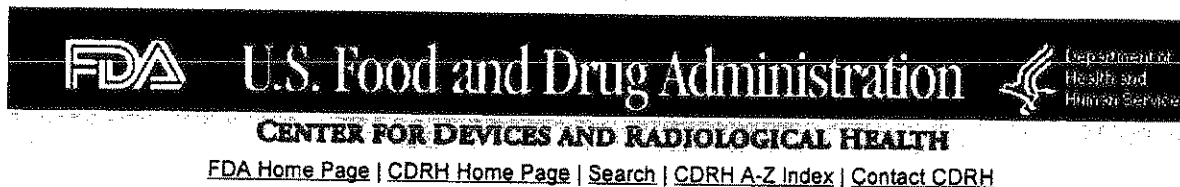
Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

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Adverse Event Report

SMITH & NEPHEW, INC./ORTHOPAEDIC DIVISION ECHELON HIP PROSTHESIS

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Catalog Number 71340117

Event Date 07/18/2000

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that during implantation of the femoral stem, a femoral fracture occurred adjacent to the distal tip of the device. Add'l surgery with a plate and cable was subsequently required for internal fixation of this fracture.

Search Alerts/Recalls

[new search](#) | [submit an adverse event report](#)

Brand Name ECHELON

Type of Device HIP PROSTHESIS

Baseline Brand Name ECHELON

Baseline Generic Name HIP PROSTHESIS

Baseline Catalogue Number 71340117

Baseline Device Family ECHELON HIP SYSTEM

Baseline Device 510(K) Number K963486

Baseline Device PMA Number

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW, INC./ORTHOPAEDIC
 DIVISION
 1450 Brooks Road
 Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC./ORTHOPAEDIC
DIVISION
1450 Brooks Road
Memphis TN 38116

Manufacturer Contact Ivan Harlan, Sr. Qa Engineer
1450 Brooks Road
Memphis, TN 38116
(901) 399 -6660

Device Event Key 287018

MDR Report Key 296527

Event Key 278508

Report Number 1020279-2000-00038

Device Sequence Number 1

Product Code JDH

Report Source Manufacturer

Source Type Health Professional

Reporter Occupation Physician

Type of Report Initial

Report Date 09/13/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 09/13/2000

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340117

Device LOT Number 90610091

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age na

Event Location Hospital

Date Manufacturer Received 08/14/2000

**Was Device Evaluated By
Manufacturer?** Device Not Returned To Manufacturer

Date Device Manufactured 06/01/1999

Is The Device Single Use? Yes

Is the Device an Implant? Yes

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

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Adverse Event Report

SMITH & NEPHEW, INC./ORTHOPAEDIC DIVISION ECHELON HIP PROSTHESIS

[back to search results](#)

Catalog Number 71340116

Event Date 08/10/2000

Event Type Injury **Patient Outcome** Hospitalization; Required Intervention

Event Description

It was reported that during implantation of the femoral stem, a fracture occurred adjacent to the distal tip of the device. Add'l surgery with a bone plate and cable was subsequently required for internal fixation of this fracture.

Search Alerts/Recalls

[new search](#) | [submit an adverse event report](#)

Brand Name ECHELON

Type of Device HIP PROSTHESIS

Baseline Brand Name ECHELON

Baseline Generic Name HIP PROSTHESIS

Baseline Catalogue Number 71340116

Baseline Device Family ECHELON HIP SYSTEM

Baseline Device 510(K) Number K963486

Baseline Device PMA Number

Baseline Preamendment? No

Transitional? No

510(K) Exempt? No

Shelf Life(Months) NA

Date First Marketed 11/27/1996

Manufacturer (Section F) SMITH & NEPHEW, INC./ORTHOPAEDIC
 DIVISION
 1450 Brooks Road
 Memphis TN 38116

Manufacturer (Section D) SMITH & NEPHEW, INC./ORTHOPAEDIC
DIVISION
1450 Brooks Road
Memphis TN 38116

Manufacturer Contact Ivan Harlan, Sr. Qa Engineer
1450 Brooks Road
Memphis, TN 38116
(901) 399 -6660

Device Event Key 287023

MDR Report Key 296532

Event Key 278513

Report Number 1020279-2000-00037

Device Sequence Number 1

Product Code JDH

Report Source Manufacturer

Source Type Health Professional

Reporter Occupation Physician

Type of Report Initial

Report Date 09/13/2000

1 Device Was Involved in the Event

1 Patient Was Involved in the Event

Date FDA Received 09/13/2000

Is This An Adverse Event Report? Yes

Is This A Product Problem Report? No

Device Operator Health Professional

Device Catalogue Number 71340116

Device LOT Number 00306935

Was Device Available For Evaluation? No

Is The Reporter A Health Professional? Yes

Was the Report Sent to FDA? No

Device Age na

Event Location Hospital

Date Manufacturer Received 08/14/2000

**Was Device Evaluated By
Manufacturer?** Device Not Returned To Manufacturer

Date Device Manufactured 03/01/2000

Is The Device Single Use? Yes

Is the Device an Implant? Yes

Is this an Explanted Device?

Type of Device Usage Initial

Database last updated on July 31, 2008

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Center for Devices and Radiological Health / CDRH

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Smith & Nephew, Inc., Orthopaedic Division
Page 1 of 3

FDA Facsimile Approval: 2/16/1999

1020279-2001-00067

UNK

FDA Use Only

A. Patient information

1. Patient id. UNK
2. Age at time of event: 70
3. Sex ☒ female ☐ male
4. Weight 90 lbs or kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event
(check all that apply)

☐ death ☐ disability
☐ life-threatening ☐ congenital anomaly
☒ hospitalization - initial or prolonged ☒ required intervention to prevent permanent impairment/damage
☐ other:

3. Date of event

9/28/2001

4. Date of this report

10/26/2001

5. Describe event or problem

It was reported that revision surgery was performed due to the breakage of the femoral component.

6. Relevant tests/laboratory data, including dates

UNK

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

UNK

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

1.

2.

2. Dose, frequency & route used

1.

2.

4. Diagnosis for use (indication)

1.

2.

6. Lot # (if known)

1.

2.

7. Exp. date (if known)

1.

2.

9. NDC # - for product problems only (if known)

1.

2.

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
EACHELON

2. Type of device
FEMORAL STEM

3. Manufacturer name & address

Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA

4. Operator of device

☒ health professional
☐ lay user/patient
☐ other:

5. Expiration date
(month/day/yr)

unk

7. If implanted, give date
(month/day/yr)

unk

8. If explanted, give date
(month/day/yr)

9/28/2001

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☒ no ☐ returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

UNK

I. Initial reporter

1. Name, address & phone #

Doug North, Smith & Nephew Surgical Pty. LTD
Block 1F
27 Paul Street North
North Ryde, nsw 2113, Australia
+61 2 9857 3913

2. Health professional?

☐ yes ☒ no Company Rep.

4. Initial reporter also sent report to FDA

☐ yes ☒ no ☐ unk



3500A - Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer, or product caused or contributed to the event.

Medication and Device**Experience Report**

(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Smith & Nephew, Inc., Orthopaedic Division
Page 2 of 3

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service - Food and Drug Administration

Set report # 1020279-2001-00067

U.F./Dist. report # UNK

FDA Use Only

I. For use by user facility/distributor/devices only

1. Check one
☒ user facility ☐ distributor

2. U.F./Dist report number
UNK

3. User facility or distributor name/address
UNK

4. Contact person
UNK

5. Phone number
UNK

6. Date user facility or distrib. became aware of event (month/year)
UNK

7. Type of report
☐ initial ☐ follow-up #

8. Date of this report (month/year)
NA

9. Approximate age of device
12 months

10. Event problem codes (refer to coding manual)
patient code
device code

11. Report sent to FDA?
☐ yes ☒ no UNK (month/year)

12. Location where event occurred
☒ hospital ☐ outpatient diagnostic facility
☐ home ☐ ambulatory surgical facility
☐ nursing home ☐ outpatient treatment facility
☐ other: _____

13. Report sent to manufacturer?
☐ yes ☒ no UNK (month/year)

14. Manufacturer name/address
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA

II. Device manufacturers only

1. Type of reportable event
☐ death
☒ serious injury
☐ malfunction (see guidelines)
☐ other: _____

2. If follow-up, what type?
☐ correction
☐ additional information
☐ response to FDA request
☐ device evaluation

3. Device evaluated by mfr?
☒ not returned to mfr.
☐ yes ☐ evaluation summary attached
☐ no (attach page to explain why not) or provide code: _____

4. Device manufacture date (month/year)
UNK

5. Labeled for single use?
☒ yes ☐ no

6. Evaluation codes (refer to coding manual)
method
results
conclusions

7. If remedial action indicated, check type
☐ recall ☐ notification
☐ repair ☐ inspection
☐ replace ☐ patient monitoring
☐ relabeling ☐ modification/adjustment
☐ other: _____

8. Usage of device
☒ initial use of device
☐ reuse
☐ unknown

9. If action reported to FDA under 21 USC 360(i), list correction/removal reporting number: _____

10. ☐ Additional manufacturer narrative and/or 11. ☐ Corrected data

III. All manufacturers

1. Contact office - name/address (& mfring site for devices)
Mr. Ivan Harlan, Reg Compliance Mgr.
Smith & Nephew, Inc., Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116 USA

2. Phone number
(901) 399-6660

3. Report source (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☒ company representative
☐ distributor
☐ other: _____

4. Date received by manufacturer (month/year)
10/02/2001

5. (A)NDA #
IND #
PLA #

6. If IND, protocol #

7. Type of report (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☒ initial ☐ follow-up #

8. Adverse event term(s)
pre-1938 ☐ yes
OTC product ☐ yes

9. Mfr. report number
1020279-2001-00067

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FDA Form 3500A - back

Report Clearance Officer, PH3
Robert H. Humphrey Building, Room 721-B
200 Independence Avenue, S.W.
Washington, DC 20201
ATTN: PRA

and to:

Office of Management and Budget

Paperwork Reduction Project (0910-0291)

Washington, DC 20503

Please do NOT return this form to either of these addresses.

**Medication and Device
Experience Report
(continued)**

Smith & Nephew, Inc., Orthopaedic Division
Page 3 of 3

Mfr report #	1020279-2001-00067
U/F/Disl. report #	UNK
FDA Use Only	

Washington, DC 20503

Additional Information